DEPARTMENT OF HEALTH AND HUMAN SERVICES

54401d

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

November 4, 2003

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 04-09

Frank D. Dulcich, President
Pacific Seafood Group
16797 SE 130th Avenue
Clackamas, Oregon 97015

WARNING LETTER

Dear Mr. Dulcich:

We inspected your firm, Pacific Smoking Company, located at 16797 SE 130th Avenue, Clackamas, Oregon, on June 10-12, 2003, as a follow-up to a surveillance sample of your smoked salmon product that was collected by FDA and subsequently found to be positive for Listeria monocytogenes. As part of that inspection, in-line and finished product samples of salmon, as well as environmental swabs from various locations within the manufacturing plant, were collected and analyzed for Listeria monocytogenes. The analysis revealed the finished and in-line products to be positive for Listeria monocytogenes. As a result, the product is adulterated within the meaning of Section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), in that it contains a deleterious substance, the bacterium Listeria monocytogenes, which may have rendered the food injurious to health.

In addition, the analysis revealed in-line samples and environmental swabs from a number of locations in your processing plant to be positive for Listeria monocytogenes. These included swabs of the tote in which salmon was thawed; the exterior of the tub in which the salmon was brined; the cutting table on which the salmon was filleted; and an in-line sample of the brine in which the salmon was processed. As a result, the smoked salmon is adulterated within the meaning of Section 402(a)(4) of the Act, in that the products were prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health.

During the inspection, we found that you had serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations). An FDA 483 form (copy enclosed) listing the deviations was presented to Kurt M. Mitchell, Operations Manager, at the conclusion of the inspection. In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a

HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your smoked salmon is adulterated, in that the product has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. You can find the Act, the seafood HACCP regulations, and FDA's Fish and Fisheries Products Hazards and Controls Guidance: Third Edition through links on FDA's home page at *www.fda.gov*. The deviations were as follows:

1. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6 (c) (3). A critical limit is defined in 21 CFR Part 123.3 (c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point (CCP) to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." You must also verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur to comply with 123.8 (a). However, your firm's HACCP plan for refrigerated vacuum packaged hot smoked salmon lists critical limits at the "Brining Injection" critical control point that have not been adequately verified and are not adequate to control Clostridium botulinum in the finished product. FDA sample results showed that there was less than 3.5 percent water phase salt in 19 of 20 finished product sub samples. FDA recommends that refrigerated vacuum packaged hot smoked salmon be processed to have a water phase salt level of not less than 3.5 percent. The adequacy of the brining process should be established by a scientific study. Critical limits should be established for other critical factors not currently addressed in your plan such as: injection brine strength and thickness of fish portions. In addition, FDA recommends finished product sampling and analysis to verify water phase salt should be done at least once every three months. Please refer to the FDA Fish and Fisheries Products Hazards and Controls Guidance (Third Edition) for further guidance.

2. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (c)(1). A food safety hazard is defined in 21 CFR Part 123.3 (f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However, your firm's HACCP plan for refrigerated vacuum packed hot smoked salmon does not list the food safety hazard of undeclared Yellow #5. Your HACCP plan must include a CCP to ensure that products with added Yellow #5 are labeled to identify the presence or this color additive.

3. You must take an appropriate corrective action when a deviation from a critical limit occurs, to comply with 21 CFR 123.7(a). However, your firm did not take a corrective action to control the hazard of Clostridium botulinum toxin formation when your process for refrigerated vacuum packaged hot smoked salmon deviated from your critical limit at the "Brining/Soaking" CCP. Specifically, your firm recorded a salt content of [redacted]% on June 11, 2003. However, no corrective action was taken even though a critical limit of [redacted]% salt content is listed in your firm's HACCP plan for refrigerated vacuum packaged hot smoked salmon at the "Brining/Soaking" CCP.

4. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7 (b). However, your corrective action plans are not appropriate for refrigerated vacuum packaged hot smoked salmon at the critical control points identified below to control the hazards of pathogen survival through cooking, pathogen growth, and toxin production. Specifically:

   a) The listed corrective action in your HACCP plan does not address correcting the cause of the deviation at the "Brine Soaking," "Brine Injection," "Smoking/Cooking," and "Chilling" critical control points.

   b) The listed corrective actions in your HACCP plan do not properly address evaluation and disposition of product exposed to a critical limit deviation at the "Cooler Storage" critical control point.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Michael J. Donovan, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact Mr. Donovan at (425) 483-4906.

Sincerely,

Kristy D. Dias
for Charles M. Breen
District Director

Enclosures:
Form FDA 483

cc: ODA with disclosure statement